Mini-Plus

Compressor Nebulizer

Model No.: 9R-021000

Please read the manual before use.

USER'S MANUAL

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CAUTION - U.S. Federal Law restricts this device to sale by or on the order of a physician.

This product has been tested and successfully approved with the following standards:

EN 60601-1
EN 60601-1-2

CE
0197

IMPORTANT SAFEGUARDS
SAVE THESE INSTRUCTIONS

READ ALL INSTRUCTIONS BEFORE USING

DANGER - To reduce the risk of electrocution:

1. Always unplug this product immediately after using.
2. Do not use while bathing, showering, dish washing, or close to water sources of any kind.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for a product that has fallen into water. Unplug immediately.

WARNING - To reduce the risk of burns, electrocution, fire or injury to persons:

1. This product should never be left unattended when plugged in.
2. Close supervision is necessary when this product is used by, on or near children or invalids.
3. Use this product only for its intended use as described in this manual. Use this product only under doctor's direction. Do not use attachments not recommended by the manufacturer.
4. Never operate this product if a) it has a damaged cord or plug, b) it is not working properly, c) it has been dropped or damaged, or d) it has been dropped into water. Return the product to a specified service center for examination and repair.
5. Keep the cord away from heated surfaces.
6. Never block the air openings of this product or allow objects to fall or be inserted into the air vent openings or place it on a soft surface such as bed or couch, where the air openings may be blocked.
7. Never use while sleeping or feeling drowsy.
8. Never drop or insert any object into any opening or hose.
9. Do not use in outdoors or operate where aerosol (spray) products are being used or where oxygen is being administered in a closed environment such as an oxygen reservoir.
10. When using any electrical appliance certain important safety measures must always be observed, including the following:

NOTE, CAUTION, WARNING STATEMENTS AND SYMBOLS:

NOTE - **Indicates information that user should pay special attention to.**

CAUTION - **Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property.**

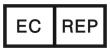
WARNING - **Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.**

EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1:2004. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

SYMBOLS -

O	Off, disconnection from the mains
I	On, connection to the mains
~	Alternating current
IPX0	Enclosed equipment without protection against ingress of water
	Manufacturer
	Authorised representative in the European community
	CAUTION should be used to highlight the fact that there are specific warnings or precautions associated with the device.
	Consult instructions for use.
	Class II
	"BF" symbol, indicate this product is according to the degree of protecting against electric shock for the type BF equipment.
	Disposal of Electrical & Electronic Equipment (WEEE): This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

1. Introduction

1.1 Intended Use

The Mini-Plus Compressor Nebulizer System is intended to provide a source of compressed air for aerosol therapy. It is used in conjunction with a jet (pneumatic) nebulizer to produce medicated aerosols for inhalation by pediatric and adult patients with respiratory symptoms.

CAUTION - Indications for therapy include asthma, chronic bronchitis, infection of the upper respiratory tract, chronic obstructive pulmonary disease and other respiratory disorders in accordance with a medical doctor's prescription. Except the usage mentioned above, please do not use this product for any other purpose. This device can be used with adults or pediatric patients under physician's prescription.

1.2 Safety Precaution Instruction

When using this electrical product, especially when children are present, one should always follow basic safety precautions. Do not install, maintain or operate this equipment without reading, understanding and following the proper Mini-Plus Compressor System instruction manual, otherwise injury or damage may result. Important information is highlighted by using the following bulletin:

DANGER- Urgent safety information for hazards that will cause serious injury or death.

WARNING- Important safety information for hazards that might cause serious injury or property damage.

CAUTION - Information for preventing damage to the product.

For 120V only-

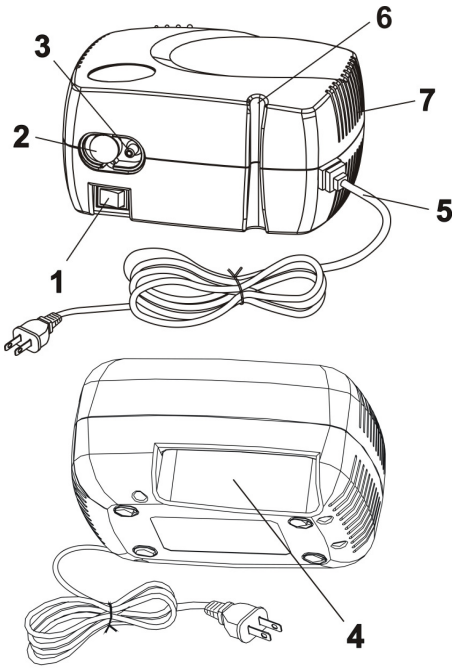
This appliance has a polarized plug (one blade is wider than the other). To reduce the risk of electric shock, this plug is intended to fit into a polarized outlet only one way. If the plug does not fit fully into the outlet, reverse the plug.

If it still does not fit, contact a qualified electrician. Do not modify the plug in any way.

2. Product Description

Compressor Main Unit

1. Power Switch
2. Filter Cap (disposable filter inside)
3. Air-Outlet Connector
4. Integrated Carrying Handle
5. Power Cord
6. Tubing Holder
7. Cooling Air Openings



3. Operation

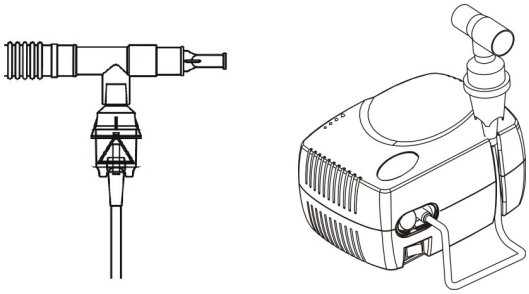
NOTE - Before initial operation, the nebulizer cup assembly should be cleaned following instructions described in the "Cleaning" section.

WARNING - Before connecting the power cord, make sure the I/O (ON/OFF) switch is in the O (OFF) position.

⚠ **The plug is also served to disconnect the device.**

3.1 Daily Use Operation

CAUTION - The Mini-Plus Compressor is designed for intermittent use only. Do not operate it continuously for more than 30 minutes for a single use without turning it off and following a cooling period for least 30 minutes.



1. Before each use inspect the Mini-Plus Compressor and nebulizer cup assembly for damage or wear, replace as needed.
2. Place the Mini-Plus Compressor on a table or other flat stable surface. Be sure you can easily reach the controls when seated. Do not use this device on the floor.
3. With the power switch in the O (OFF) position, plug the power cord into an appropriate electrical wall outlet.
4. Connect one end of the tubing to the compressor air-outlet connector.
5. Assemble the nebulizer cup and add indicated medication to the nebulizer's cup before use.
6. Attach the other end of the tubing into the air-inlet connector founded at the bottom of the nebulizer cup.
7. Turn on the Mini-Plus Compressor by pressing the power switch to the I (ON) position and begin treatment.
8. If treatment needs to be interrupted, simply press power switch to O (OFF) position.
9. When the treatment is complete, turn off the compressor by pressing the power switch to O (OFF) position and unplug the unit from the electrical outlet.

⚠ **Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. This device has no AP or APG protection.**

3.2 Safety Overload

NOTE - Do not exceed 30 minutes of continuous operation.

1. The motor of this device has a built-in thermal overload protector. Should the motor overheat, the protector will automatically shut off the motor. Should this occur, turn the I/O (ON/OFF) switch to the O (OFF) position and allow the motor to cool down for approximately 30 minutes before turn it on again.
2. If the overload protector shuts off the motor frequently, you may have an unstable voltage situation.
3. If the unit shuts down and cannot restart, it may need to be replaced. Call your provider immediately.

4. Cleaning

4.1 Compressor Outer Case Cleaning

WARNING - Electric shock hazard. Do not remove outer case of this unit. All disassembly and maintenance of this unit must be done by a qualified service technician. Refer servicing to qualified service personnel.

WARNING - This unit does not require oil. Do not attempt to lubricate any internal parts.

WARNING - Unplug unit before cleaning. Do not submerge in water for cleaning.

1. Wipe the main unit with a damp cloth every few days to keep it dust-free.
2. Do not use any powdered type cleaners or soap. Do not submerge the unit into water.

4.2 Nebulizer Cup Cleaning

All parts of the disposable nebulizer, except tubing, should be thoroughly cleaned after each use. If your doctor specifies a specific cleaning procedure, follow that procedure.

WARNING - To prevent possible risk of infection from contaminated medication, cleaning of the nebulizer is recommended after each treatment.

1. After each use, disassemble the nebulizer cup, tee and mouthpiece completely, wash all parts in warm soapy water and rinse thoroughly. Allow to air dry. Store in a clean dry location.
2. Once daily, after washing as above, soak nebulizer components in a fresh solution consisting of one part warm water and one part white vinegar for 30 minutes followed by a warm water rinse.

NOTE - The disposable nebulizer kit is for single patient use only.

NOTE - Please follow national requirements to dispose the unit properly.

5. Storage

Keep the unit and accessories dry. Avoid direct sunshine.

6. Maintenance

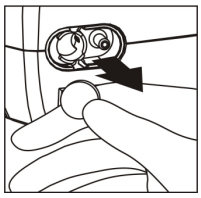
6.1 General Information

1. This unit is oil-less. Do Not Lubricate.
2. Risk of electric shock. Do not disassemble the main unit.
3. All maintenance must be performed by a qualified service personnel.

6.2 Filter Change

NOTE - Change the filter once every month or when filter turns gray.

1. Open the filter cap.
2. Remove dirty filter with a small, pointed object. Discard the filter.
3. Replace with a clean filter. Additional filters should be purchased from your provider.
4. Put the filter cap back.



CAUTION - **Do not use cotton or any other material as a filter. Do not wash or reuse the filter. Do not operate the unit without a filter.**

6.3 Fuse Change

NOTE – Use identical fuse with correct rating recommended by manufacturer.

1. Use a coin, unscrew the fuse cover in the bottom of the device.
2. Remove the fuse from the fuse cover.
3. Insert new fuse with correct rating recommended by manufacturer.
4. Screw the fuse cover back into position.

7. Troubleshooting

If your Mini-Plus Compressor Nebulizer fails to function, consult the Troubleshooting guide below. If the problem persists, consult your equipment provider.

Problem	Cause and Solution
Device doesn't operate.	• Check if plug is properly fit into an appropriate electrical outlet. • When device has been run continuously for over 30 minutes right before using, an auto shut down may activate by built-in thermal protector, cool down device for 30 minutes before next usage. • Check if fuse is blown and properly situated. (see "Maintenance" section for details)
Weak Nebulization	• Check for proper electrical voltage. • Check tubing for blockage or air leakage at connection to Mini-Plus compressor or nebulizer cup, replace as needed. • Check the nebulizer cup if it is properly assembled and not damaged. If there is any damage, replace as needed. • Check if filter is too dirty, replace as needed.

8. Specifications

Electrical Rating **(Note: Refer to the rating label on the product)**		◆ 120VAC,60Hz,1.2A
Maximum Compressor Pressure		≧35 psi
Operation Flow Rate		≧5.5lpm
Nebulization Rate		0.2~ 0.3 ml/min*
Particle size		0.5 ~ 5 microns (μm)*
Classification		Class II. BF equipment. IPXO. No AP/APG protection.
Applied part		Mouthpiece or Nasal mask
Dimensions (W x D x H)		14.0 x 18.8 x 10.0 cm / 5.5" x 7.4" x 3.9"
Weight		1.6 kg / 3.5 lb
Fuse		T5A 250VAC for 120V system
Environment	**Temperature**	Operation: 10º C to 40º C / 50º F to 104º F Storage: -15º C to 50º C / 5º F to 122º F Transport: -15º C to 70º C / 5º F to 158º F
	Humidity	Operation: 10% to 90% RH non-condensing Storage: 10% to 90% RH non-condensing Transport: 10% to 90% RH non-condensing

Note:

1. ***Values are determined by supplier's nebulizer.**
2. **Consult distributor(s) or EU representative(s) for additional technical documents.**
3. **The Nebulizer is fitted with a fuse as specified in the Specification column, it is designed to be maintained by the manufacturer or its agents. Users are not allowed to open the cover to replace a blown fuse.**

Appendix A: EMC Information

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
Harmonic emissions IEC61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC61000-4-4	±2kV for power supply line ±1kV for input/out line	±2kV for power supply line ±1kV for input/out line	Mains power quality should be that of atypical commercial or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % U_T (>95 % dip in U_T)for 0,5 cycle 40 % U_T (60 % dip in U_T)for 5 cycles 70 % U_T (30 % dip in U_T)for 25 cycles <5 % U_T (>95 % dip in U_T)for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of atypical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.5G MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b]
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d].
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device:

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

EC REP

APEX MEDICAL S.L.
Elcano 9, 6ª planta
48008 Bilbao. Vizcaya. Spain

APEX MEDICAL CORP.
No.9, Min Sheng St., Tu-Cheng,
New Taipei City, 23679, Taiwan

Manufacturing Facility:

Apex Medical (Kunshan) Corp.
No. 1368, Zi Zhu Rd.,Kunshan Kai Fa Hi-Tech,
Kunshan City, JiangSu Sheng, China

www.apexbrand.com

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